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MARKED-UP VERSION OF AMENDMENTS:Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

Claims 1-3, 22-25, 30-31, 33, 44, 49, 52, 56-58, 61, 63, and 66 are amended.

1. (Thrice Amended) A bioadhesive composition which comprises an aqueous plasticised three dimensional polymeric matrix and a hydrophobic polymer, said aqueous plasticised three-dimensional polymeric matrix comprising up to 50% by weight of a plasticiser other than water and said matrix being the product of a polymerisation reaction performed in the presence of water, said plasticiser and said hydrophobic polymer, wherein [the] concentration of said hydrophobic polymer at [the] surface of said matrix is greater than [said]concentration of said hydrophobic polymer inside said matrix.
2. (Thrice Amended) A bioadhesive composition according to claim 1 wherein said concentration of said hydrophobic polymer at [the] surface of said matrix is four times greater than said concentration of said hydrophobic polymer inside said matrix.
3. (Thrice Amended) A bioadhesive composition according to claim 2 wherein said concentration of said hydrophobic polymer at [the] surface of said matrix is eight times greater than said concentration of said hydrophobic polymer inside said matrix.
4. A bioadhesive composition according to claim 1, comprising:
 - (i) a water activity in the range of 0.4 to 0.9;
 - (ii) an elastic modulus at 1 rad/s in the range of 700 to 15,000 Pa;
 - (iii) an elastic modulus at 100 rad/s in the range of 2000 to 40,000 Pa;
 - (iv) a viscous modulus at 1 rad/s in the range of 400 to 14,000 Pa; and
 - (v) a viscous modulus at 100 rad/s in the range of 1000 to 35,000 Pa.
5. A bioadhesive composition according to claim 1, obtained by polymerising a reaction mixture comprising:
 - (a) one or more monomers comprising a hydrophilic unsaturated water soluble acrylamido monomer;

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- (b) a hydrophobic polymer; and
(c) plasticiser.
6. A bioadhesive composition according to claim 5 obtained by polymerising a reaction mixture comprising (a) 20% to 55% by weight of said one or more monomers comprising a hydrophilic unsaturated water-soluble acrylamide monomer, (b) 0.1% to 10% by weight of said hydrophobic polymer and (c) 35% to 70% by weight of said plasticiser.
- 10 7. A bioadhesive composition according to claim 5 or claim 6 wherein said one or more monomers further comprise an ionic hydrophilic unsaturated water-soluble monomer or a non-ionic hydrophilic unsaturated water-soluble monomer.
- 15 8. A bioadhesive composition according to claim 1 wherein said hydrophobic polymer is a hydrophobic pressure sensitive adhesive.
9. A bioadhesive composition according to claim 5 wherein the reaction mixture additionally comprises from 1 to 10% by weight of a crosslinker.
- 20 10. A bioadhesive composition according to claim 9 wherein said crosslinker is selected from the group consisting of tripropylene glycol diacrylate, ethylene glycol dimethacrylate, triacrylate, polyethylene glycol diacrylate, methylene bis acrylamide, and combinations thereof.
- 25 11. A bioadhesive composition according to claim 5 wherein said reaction mixture additionally comprises an interpenetrant polymer in an amount from 1 to 6% by weight.
12. A bioadhesive composition according to claim 11 wherein the interpenetrant polymer is selected from the group consisting of poly 2-acrylamido-2-methyl-propene sulphonic acid (AMPS), poly 3-sulpho-propyl acrylate (SPA), a copolymer of sodium salt of 2-acrylamido-2-methyl-propene sulphonic acid (NaAMPS) and SPA, polyacrylic acid, polymethacrylic acid, polyethylene oxide,

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polyvinyl methyl ether, polyvinyl alcohol, polyvinylpyrrolidone, its copolymers with vinyl acetate, dimethylaminoethyl methacrylate, terpolymers with dimethylaminoethyl methacrylate and vinylcaprolactam, natural polysaccharides, synthetic polysaccharides, carboxymethyl cellulose, sodium carboxymethyl cellulose, hydroxypropylmethyl cellulose, hydroxyethyl cellulose and combinations thereof.

13. A bioadhesive composition according to claim 5 wherein said reaction mixture additionally comprises from 1 to 7% by weight of a salt.

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15. A pair of biomedical electrodes which comprise a bioadhesive composition according to claim 1.

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16. A pair of biomedical electrodes according to claim 15 which are Ag/AgCl biomedical electrodes.

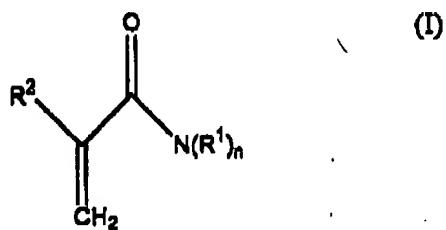
18. A fixation product for attaching a biomedical device to skin which comprises a bioadhesive composition according to claim 1.

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19. A wound dressing which comprises a carrier material in association with a bioadhesive composition of claim 1.

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21. A bioadhesive composition according to claim 1, wherein said three dimensional polymeric matrix comprises a polymer or copolymer of a hydrophilic water-soluble acrylamido monomer of formula



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wherein: n represents 2 or 3, provided that when n represents 3 a counterion is also present; R¹ represents H, C₁₋₄-alkyl or R⁸SO₃M wherein R⁸ represents an optionally substituted hydrocarbon moiety and M represents hydrogen or a cation, each R¹ being mutually the same or different; and R² is hydrogen or optionally substituted methyl or ethyl.

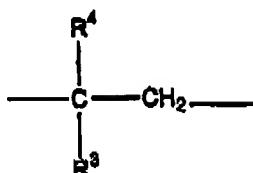
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22. (Amended) A bioadhesive composition according to claim 21, wherein in [the compound] said hydrophilic water-soluble acrylamido monomer of formula I, said hydrocarbon moiety or said methyl or ethyl group, when substituted, is substituted by a substituent selected from the group consisting of hydroxyl, amino, ammonium and halogen.
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23. (Amended) A bioadhesive composition according to claim 21, wherein in [the compound] said hydrophilic water-soluble acrylamido monomer of formula I, said cation, when present, is an alkali metal cation.
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24. (Amended) A bioadhesive composition according to claim 21, wherein in [the compound] said hydrophilic water-soluble acrylamido monomer of formula I: n represents 2; R¹ represents H or R⁸SO₃M wherein R⁸ represents an optionally substituted hydrocarbon moiety and M represents hydrogen or a cation, each R¹ being mutually the same or different; and R² is hydrogen or optionally substituted methyl or ethyl.
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25. (Amended) A bioadhesive composition according to claim 21, wherein in [the compound] said hydrophilic water-soluble acrylamido monomer of formula I at least one R¹ represents R⁸SO₃M wherein R⁸ represents an optionally substituted alkyl, cycloalkyl or aromatic moiety and M represents hydrogen or a cation.
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26. A bioadhesive composition according to claim 25, wherein R⁸ contains from 3 to 12 carbon atoms.
27. A bioadhesive composition according to claim 25, wherein R⁸ contains from 3 to 6 carbon atoms.

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28. A bioadhesive composition according to claim 25, wherein R⁸ represents a moiety of the formula



5 wherein R³ represents hydrogen or an optionally substituted straight or branched chain alkyl group possessing from 1 to 6 carbon atoms and R⁴ represents an optionally substituted straight or branched chain alkyl group possessing from 1 to 6 carbon atoms.

- 10 29. A bioadhesive composition according to claim 28, wherein in said R⁸ moiety said straight or branched chain alkyl group, when present, is substituted by a substituent selected from the group consisting of hydroxyl, amino, ammonium and halogen.

- 15 30. (Amended) A bioadhesive composition according to claim 21, wherein in [the compound] said hydrophilic water-soluble acrylamido monomer of formula I: n represents 3; R¹ represents H or C₁₋₄-alkyl, each R¹ being mutually the same or different; and R² is hydrogen or optionally substituted methyl or ethyl.

- 20 31. (Amended) A bioadhesive composition according to claim 21, wherein said hydrophilic [unsaturated] water-soluble acrylamido monomer comprises 2-acrylamido-2-methylpropane sulphonic acid or a salt thereof.

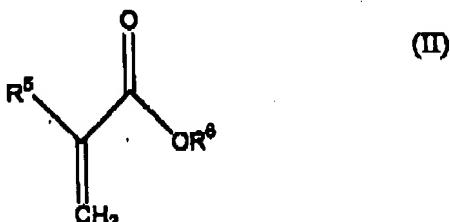
- 25 32. A bioadhesive composition according to claim 31, wherein said salt is selected from the group consisting of sodium, potassium and lithium salts.

33. (Amended) A bioadhesive composition according to claim 21, wherein said hydrophilic [unsaturated] water-soluble acrylamido monomer comprises (3-acrylamidopropyl) trimethyl ammonium chloride.

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34. A bioadhesive composition according to claim 21, wherein said three dimensional polymeric matrix further comprises a polymer or copolymer of an ionic or non-ionic hydrophilic unsaturated water-soluble monomer compound of formula



5 wherein: R⁵ represents hydrogen or optionally substituted methyl or ethyl; and R⁶ represents hydrogen, a cation or R⁷SO₃, wherein R⁷ represents an optionally substituted alkylene moiety of 1 to 4 carbon atoms.

- 10 35. A bioadhesive composition according to claim 34, wherein said methyl or ethyl group or said alkylene moiety, when present, is substituted by a substituent selected from the group consisting of hydroxyl, amino, ammonium and halogen.
- 15 36. A bioadhesive composition according to claim 34, wherein R⁷ represents an optionally substituted n-propyl group.
- 20 37. A bioadhesive composition according to claim 34, wherein said ionic hydrophilic unsaturated water-soluble monomer is selected from the group consisting of acrylic acid or an ester or salt thereof, a polymerisable sulphonate or salt thereof, and mixtures thereof.
- 25 38. A bioadhesive composition according to claim 37, wherein said ionic hydrophilic unsaturated water-soluble monomer comprises acrylic acid (3-sulphopropyl) ester or a salt thereof.
39. A bioadhesive composition according to claim 38, wherein said salt is selected from the group consisting of sodium, potassium and lithium salts.

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40. A bioadhesive composition according to claim 1, wherein said hydrophobic polymer is selected from the group consisting of a polyacrylate, a polyolefin, a silicone adhesive, a natural rubber, a synthetic rubber, a polyvinyl ether, and mixtures thereof.
- 5 41. A bioadhesive composition according to claim 1, wherein said hydrophobic polymer comprises a vinyl acetate dioctyl maleate copolymer.
- 10 42. A bioadhesive composition according to claim 1, wherein said hydrophobic polymer comprises an ethylene vinyl acetate copolymer.
43. A bioadhesive composition according to claim 1, wherein said aqueous plasticised three dimensional polymeric matrix includes an aqueous plasticising medium.
- 15 44. (Amended) A bioadhesive composition according to claim 43, wherein said aqueous plasticising medium comprises water and a plasticiser, said plasticiser is selected from the group consisting of a polyhydric alcohol, an ester derived therefrom, a polymeric alcohol, and mixtures thereof.
- 20 45. A bioadhesive composition according to claim 5, wherein said plasticiser comprises water and a plasticiser selected from the group consisting of a polyhydric alcohol, an ester derived therefrom, a polymeric alcohol, and mixtures thereof.
- 25 46. A bioadhesive composition according to claim 1, further comprising an additional component selected from the group consisting of crosslinkers, interpenetrant polymers, surfactants, electrolytes, processing aids, antimicrobial agents, pharmaceutically active agents and mixtures thereof.
- 30 47. A bioadhesive composition according to claim 1, obtained by polymerising a reaction mixture comprising (a) a monomer mixture comprising a hydrophilic unsaturated water-soluble acrylamido monomer and an ionic monomer selected from the group consisting of acrylic acid, an ester or salt thereof, a polymerisable

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sulphonate or salt thereof, and mixtures thereof, (b) a hydrophobic polymer, and (c) a plasticiser.

48. A bioadhesive composition according to claim 5 or 47, wherein said plasticiser comprises water and a plasticiser selected from the group consisting of a polyhydric alcohol, an ester derived therefrom, a polymeric alcohol and mixtures thereof.

5 49. (Amended) A bioadhesive composition according to claim 5 [or 7], wherein said reaction mixture further includes components selected from the group consisting of crosslinkers, interpenetrant polymers, surfactants, electrolytes, processing aids, 10 antimicrobial agents, pharmaceutically active agents and mixtures thereof.

15 50. A bioadhesive composition according to claim 47, wherein said hydrophobic polymer comprises a vinyl acetate dioctyl maleate copolymer.

51. A bioadhesive composition according to claim 47, wherein said hydrophobic polymer comprises an ethylene vinyl acetate copolymer.

20 52. (Amended) A biomedical electrode comprising an electrically conductive interface member adapted to be connected electrically to an item of medical equipment and an electrically conductive medium associated with the interface member for adhering to a patient's skin, wherein said electrically conductive medium comprises a bioadhesive composition comprising an aqueous plasticised three dimensional polymeric matrix and a hydrophobic polymer said aqueous plasticised
25 three-dimensional polymeric matrix comprising up to 50% by weight of a plasticiser
other than water and said matrix being the product of a polymerisation reaction
performed in the presence of said water, said plasticiser and said hydrophobic
polymer, wherein [the]concentration of said hydrophobic polymer at [the]surface of
30 said matrix is greater than [said] concentration of said hydrophobic polymer inside
said matrix.

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53. A biomedical electrode according to claim 52, wherein said electrically conductive interface comprises a layer of an electrically conductive material applied to a support member.

5 54. A biomedical electrode according to claim 52, wherein said bioadhesive composition is obtained by polymerising a reaction mixture comprising (a) one or more monomers comprising a hydrophilic unsaturated water soluble acrylamido monomer; (b) a hydrophobic polymer; and (c) a plasticiser.

10 55. A biomedical electrode according to claim 52, wherein said bioadhesive composition is obtained by polymerising a reaction mixture comprising (a) a monomer mixture comprising a hydrophilic unsaturated water-soluble acrylamido monomer and an ionic monomer selected from the group consisting of acrylic acid, an ester or salt thereof, a polymerisable sulphonate or salt thereof, and mixtures thereof, (b) a hydrophobic polymer, and (c) a plasticiser.

15 56. (Amended) A biomedical electrode according to claim [52 or 53]54 or 55, where said plasticiser is mixed with [comprises] water and [a]said plasticiser is selected from the group consisting of a polyhydric alcohol, an ester derived therefrom, a polymeric alcohol and mixtures thereof.

20 57. (Amended) A biomedical electrode according to claim [52 or 53]54 or 55, wherein said reaction mixture further includes components selected from the group consisting of crosslinkers, intrepenerant polymers, surfactants, electrolytes, processing aids, antimicrobial agents, pharmaceutically active agents and mixtures thereof.

25 58. (Amended) A fixation product for attaching a catheter, tubing, wires or cables to skin, wherein a bioadhesive composition is provided at a point of said attachment, said bioadhesive composition comprising an aqueous plasticised three dimensional polymeric matrix and a hydrophobic said aqueous plasticised three-dimensional polymeric matrix comprising up to 50% by weight of a plasticiser other than water and said matrix being the product of a polymerisation reaction performed in

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the presence of water, said plasticiser and said hydrophobic polymer, wherein [the]
concentration of said hydrophobic polymer at [the] surface of said matrix is greater
than [said] concentration of said hydrophobic polymer inside said matrix.

- 5 59. A fixation product according to claim 58, wherein said bioadhesive composition is obtained by polymerising a reaction mixture comprising: (a) one or more monomers comprising a hydrophilic unsaturated water soluble acrylamido monomer; (b) a hydrophobic polymer; and (c) a plasticiser.
- 10 60. A fixation product according to claim 58, wherein said bioadhesive composition is obtained by polymerising a reaction mixture comprising (a) a monomer mixture comprising a hydrophilic unsaturated water-soluble acrylamido monomer and an ionic monomer selected from the group consisting of acrylic acid, an ester or salt thereof, a polymerisable sulphonate or salt thereof, and mixtures thereof, (b) a hydrophobic polymer, and (c) a plasticiser.
- 15 61. (Amended) A fixation product according to claim 59 or 60, wherein said plasticiser [comprises] is mixed with water, and [a]said plasticiser is selected [selected] from the group consisting of a polyhydric alcohol, an ester derived therefrom, a polymeric alcohol and mixtures thereof.
- 20 62. A fixation product according to claim 59 or 60, wherein said reaction mixture further includes components selected from the group consisting of crosslinkers, interpenetrant polymers, surfactants, electrolytes, processing aids, antimicrobial agents, pharmaceutically active agents and mixtures thereof.
- 25 63. (Amended) A wound dressing comprising a carrier material encapsulated or coated by a bioadhesive composition comprising an aqueous plasticised three dimensional polymeric matrix and a hydrophobic polymer, said aqueous plasticised three-dimensional polymeric matrix comprising up to 50% by weight of a plasticiser other than water and said matrix being the product of a polymerisation reaction performed in the presence of water, said plasticiser and said hydrophobic polymer, wherein [the] concentration of said hydrophobic polymer at [the] surface of said

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matrix is greater than [said] concentration of said hydrophobic polymer inside said matrix.

64. A wound dressing according to claim 63, wherein said bioadhesive composition is obtained by polymerising an aqueous reaction mixture comprising: (a) one or more monomers comprising a hydrophilic unsaturated water soluble acrylamido monomer; (b) a hydrophobic polymer; and (c) a plasticiser.

65. A wound dressing according to claim 63, wherein said bioadhesive composition is obtained by polymerising an aqueous reaction mixture comprising (a) a monomer mixture comprising a hydrophilic unsaturated water-soluble acrylamido monomer and an ionic monomer selected from the group consisting of acrylic acid, an ester or salt thereof, a polymerisable sulphonate or salt thereof, and mixtures thereof, (b) a hydrophobic polymer, and (c) a plasticiser.

66. (Amended) A wound dressing according to claim 64 or 65, wherein said plasticiser [comprises] is mixed with water and [a] said plasticiser is selected from the group consisting of a polyhydric alcohol, an ester derived therefrom, a polymeric alcohol and mixtures thereof.

67. A wound dressing according to claim 64 or 65, wherein said aqueous reaction mixture further includes components selected from the group consisting of crosslinkers, interpenetrant polymers, surfactants, electrolytes, processing aids, antimicrobial agents, pharmaceutically active agents and mixtures thereof.

68. A wound dressing according to claim 64 or 65, when prepared by coating or encapsulating said carrier material with said aqueous reaction mixture, said aqueous reaction mixture comprising first and second monomers and a crosslinking agent, and curing said coating on said carrier material.

69. A wound dressing according to claim 63, when prepared by coating said carrier material with said bioadhesive composition.

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70. A bioadhesive composition obtained by polymerising an aqueous reaction mixture comprising (a) a monomer mixture comprising a hydrophilic unsaturated water-soluble acrylamido monomer and an ionic monomer selected from the group consisting of acrylic acid, an ester or salt thereof, a polymerisable sulphonate or salt thereof, and mixtures thereof, (b) a hydrophobic polymer, and (c) a plasticiser.
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71. A bioadhesive composition according to claim 70, wherein said plasticiser comprises water and a plasticiser selected from the group consisting of a polyhydric alcohol, an ester derived therefrom, a polymeric alcohol and mixtures thereof.
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72. A bioadhesive composition according to claim 70, wherein said aqueous reaction mixture further includes components selected from the group consisting of crosslinkers, interpenetrant polymers, surfactants, electrolytes, processing aids, antimicrobial agents, pharmaceutically active agents and mixtures thereof.